

REMARKS

The invention

The invention relates to the discovery of families of peptide compounds, members of which possess antiarrhythmic activity. Applicants have synthesized numerous peptides falling within the families and have tested peptides for antiarrhythmic activity in *in vitro* and *in vivo* assays.

The Office action

Prior to the present reply, claims 1-162 were pending. Due to a restriction requirement, the Office has withdrawn claims 1-40, 50-51, and 156-162 from consideration. The Office also indicates that claims 41, 47, 49, and 50 have been examined. Claims 47, 49, and 50 are objected to under 37 C.F.R. § 1.75(c) for improper multiple dependencies. Claims 41, 47, 49, and 50 are rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. Claim 41 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 41, 47, 49, and 50 are rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,817,316 (hereafter “Sodroski”). The objection and each of these rejections are addressed below.

Claim amendments

Claims 41, 47, 50-52, and 55 have been amended. Withdrawn claims 1-40 and 56-162 have been cancelled. New claims 163-193 have been added. Claim 41 has been amended to recite the structures of formulas II and IIa. Support for this change is found, for example, at page 12, lines 1-12.¹ Claim 47 has been amended for clarity. Claims 50 and 51 have been amended to depend from claim 41. Claim 50 has also been amended for clarity. Claims 52 and 55 have been amended for clarity. New claims 163 and 164 recite specific limitations on the peptide of formula XII. Support for these claims is found, for example, in original claim 41. Claim 165 recites cyclo(-Gly-Ala-Gly-Hyp-Pro-Tyr-Asn-) (SEQ ID NO:287). Support for this claim is found, for example, at page 138, line 10. Support for the compounds recited in claims 166-193 can be found in original claim 41. No new matter has been added by the present amendments.

Amendment to the title

Applicants amended the title of the application in their reply to Restriction Requirement mailed November 27, 2006. The Office has not acknowledged entry of this amendment, nor does the PAIR system reflect the amended title. Applicants therefore submit a supplemental Application Data Sheet reflecting the amended title with the present reply. Entry of this amendment is respectfully requested.

¹All page numbers and line numbers recited herein refer to the page and line numbers of replacement specification filed December 16, 2004.

The restriction requirement

The Office indicates that claims 41, 47, 49, and 50 have been examined on the merits, but the Office also indicates that claim 50 is drawn to a non-elected invention. As noted above, Applicants have amended claims 50 and 51 to depend from claim 41, and submit that these claims are properly considered in the present application.

Claim objections

The Office objects to claims 47, 49, and 50 as being in improper multiple dependent form. Applicants note that these claims were amended in the Preliminary Amendment filed November 8, 2004 into proper dependent form. Accordingly, this objection may be withdrawn.

Rejection under 35 U.S.C. § 112, written description

The Office rejects claims 41, 47, 49, and 50 as failing to comply with the written description requirement. Applicants respectfully traverse this rejection.

The written description of a genus may be achieved by recitation of a representative number of species falling within the genus. In the action, the Office asserts that the application discloses only a single member of the claimed genus, i.e., SEQ ID NO:287 (cyclo(-Gly-Ala-Gly-Hyp-Pro-Tyr-Asn-)). On this point, the Office is incorrect. Applicants direct the Office's attention to pages 121-145 of the specification. These

pages describe the synthesis of many peptides falling within the peptide formula XII.

Such peptides include, for example, compounds 2-14, 22-26, 31, 32, and 35-44. This basis for the written description rejection should be withdrawn.

The Office further asserts that the specification gives little to no guidance for the retro forms, the all-D forms, and retro all-D forms of the peptide of formula XII. Applicants respectfully disagree. Applicants again direct the Office to pages 121-145 of the specification. Retro forms of peptides of formula XII include, for example, compounds 2-4, 24-26, 35, 36, 38, and 44. All-D forms of peptides of formula XII include, for example, compounds 2 and 22-26. Retro all-D forms of the peptide include, for example, compounds 2 and 24-26. In view of this disclosure, Applicants submit that this basis for the written description rejection should also be withdrawn.

The Office further rejects the claims on the basis that one cannot expect the same results from two different peptides and notes that single point mutations can result in differing biological activities. Applicants do not disagree that a single point mutation in a peptide can alter function; however, the claimed peptides are limited by their structural characteristics, not by their function. Accordingly, Applicants submit that the Office's concern in this regard is unwarranted. This basis for the written description rejection should also be withdrawn.

For all of these reasons, Applicants submit that they have disclosed a sufficient number of species to constitute the claimed genus and have accordingly demonstrated

their possession of the claimed invention. On this basis, Applicants respectfully request that the written description rejection be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

Claim 41 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for reciting a moiety of formula II or IIa where the formulas have not been defined. Applicants have accordingly amended claim 41 to recite definitions for these formulas. This rejection may therefore be withdrawn.

Rejection under 35 U.S.C. § 102(b)

The Office rejects claims 41, 47, 49, and 50 as anticipated by Sodroski. Applicants respectfully traverse this rejection.

To anticipate a claim, a reference must disclose each and every limitation of that claim. Sodroski discloses a polypeptide that includes conserved regions of the gp120 polypeptide joined by a Gly-Ala-Gly linker sequence. By contrast, formula XII of claim 41 requires that the N-terminal amino acid of the peptide be linked to the moiety X (i.e., a photoprobe capable of being bonded to the amino terminal, an acyl group derived from a C(2-22)alkyl carboxylic acid, such as acetic acid, propionic acid, butyric acid and other fatty acids, such as behenic acid, optionally substituted with one or more substituents selected from the group consisting of hydroxy, halogen, C(1-6)alkyl, nitro and cyano, or

hydrogen). Formula XII of claim 41 also requires that the C-terminal amino acid of the peptide be linked to the moiety R₇ (i.e., OH, NH₂, NHNH₂ or OR₈, where R₈ represents H, a straight or branched C(1-6)alkyl group, an aryl or an aralkyl group) when the bond between N* and C* is missing, or alternatively, R₇ is absent when there is a bond between N* and C*. Thus a Gly-Ala-Gly peptide of claim 41 can be represented as **X-Gly-Ala-Gly-R₇**. By contrast, Sodroski only teaches a Gly-Ala-Gly sequence that can be represented by **[gp120 sequence]-Gly-Ala-Gly-[gp120 sequence]**. As neither X nor R₇ can be a gp120 sequence, Sodroski fails to teach each and every limitation of claim 41 or its dependent claims. Accordingly, this reference cannot anticipate the claims. The rejection under 35 U.S.C. § 102(b) over Sodroski may be withdrawn.

CONCLUSION

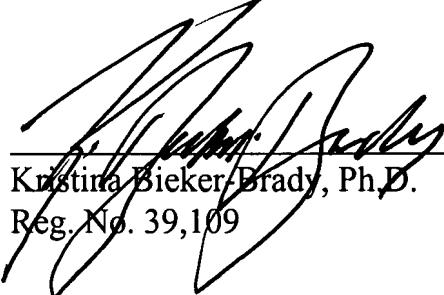
Applicants submit the claims are in condition for allowance and such action is respectfully requested. Enclosed is a Petition to extend the period for replying to the Office action for three (3) months, to and including September 27, 2007, and a check in payment of the required extension fee.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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